

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 1, 12-35, and 42 are pending and directed to an isolated polypeptide (claim 1), a ligand that recognizes the polypeptide (claims 12-19 and 33-35), a composition comprising the ligand (claims 20-30), and a method for treating a cancer disease (claims 31, 32, and 42).

Claim 1 is the sole claim under examination at the present time. Claims 12-35 and 42 are labeled as withdrawn in response to the earlier restriction requirement. Applicants request the rejoinder and examination of claims 12-35 and 42 at such time as claim 1 is indicated as allowable inasmuch as claims 12-35 and 42 directly or indirectly depend from, or contain the same limitation as, claim 1.

Amendments to the Title

The title has been amended to recite "nmMHCA Polypeptides." No new matter has been added by way of this amendment to the title.

Amendments to the Claims

The claims have been amended to point out more particularly and claim more distinctly the invention. In particular, claim 1 has been amended to recite that the polypeptide consists of the amino acid sequence of SEQ ID NO: 20, 21, or 22. The amendment to claim 1 is supported by the specification at, for example, page 23, lines 11-14, and original claim 11. No new matter has been added by way of this amendment to the claim.

Summary of the Office Action

The Office rejects claim 1 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description.

The Office objects to the specification, because the title allegedly is not descriptive.

The Office rejects claim 1 under 35 U.S.C. § 103(a) as allegedly unpatentable over Toothaker et al. (*Blood*, 78(7):1826-1833 (1991)) and Kelly et al. (*Nat. Genet.*, 26:106-108 (2000)).

Reconsideration of the objections and rejections is hereby requested.

Discussion of the Written Description Rejection

The Office believes that Applicants did not contemplate (and the application does not explicitly disclose) an isolated polypeptide consisting of amino acids 600-1,960 of SEQ ID NO: 17, as recited in claim 1. Applicants traverse this rejection for the following reasons.

Claim 1, as amended, recites an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO: 20, 21, or 22. The specification describes such a polypeptide, as well as the synthesis of the polypeptide, in Example 3 (see, e.g., page 23, lines 11-14).

Thus, the subject matter of claim 1 is adequately described in the specification, and the written description rejection should be withdrawn.

Discussion of the Objection to the Specification

The Office contends that the title is not descriptive of the claimed invention. As suggested by the Office, Applicants have amended the title to recite “nmMHCA Polypeptides.” Applicants believe that the objection to the specification is moot in view of the amendment to the title.

Discussion of the Obviousness Rejection

The Office contends that it would have been obvious to one of ordinary skill in the art to arrive at the polypeptide of claim 1 based on the teachings of the Toothaker and Kelley references. The obviousness rejection is traversed for the following reasons.

For subject matter defined by a claim to be considered obvious, the Office must demonstrate that the differences between the claimed subject matter and the prior art “are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”

35 U.S.C. § 103(a); see also *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). The ultimate determination of whether an invention is or is not obvious is based on certain factual inquiries including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the prior art, (3) the differences between the claimed invention and the prior art, and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18, 148 U.S.P.Q. at 467.

Consideration of the aforementioned *Graham* factors here indicates that the present invention, as defined by the pending claims, is unobvious in view of the cited references.

As regards the scope and content of the prior art, the Office contends that that Toothaker et al. discloses the full length nmMHCA sequence that comprises residues 600-1960, as well as the putative domains of the nmMHCA protein. Toothaker et al. identifies residues 836-1961 as the carboxyl terminal rod (as opposed to residues 600-1960 of SEQ ID NO: 17).

The Office contends that Kelley et al. discloses domains of myosin heavy chains, and mutations at residues 1841 and 1155 that are associated with MHA-associated disorders. The Office considers that one of ordinary skill in the art would be motivated to clone and isolate the section of nmMHCA consisting of residues 600-1960 of SEQ ID NO: 17 to use as a comparison for mutations for MHA-associated disorders.

For purposes of the analysis here, and for the sake of argument, the level of ordinary skill can be considered to be relatively high, such that a person of ordinary skill in the art would have an advanced degree and/or several years of experience in the relevant field.

Claim 1, as amended, is directed to an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO: 20, 21, or 22. Each of SEQ ID NOs: 20, 21, and 22 consists of 10 amino acids. Applicants have described the synthesis of a polypeptide consisting of the amino acid sequence of each of SEQ ID NO: 20, 21, and 22 in Example 3.

There is no teaching or suggestion in any of the cited references, and the Office provides no credible reason for one of ordinary skill in the art, to select a polypeptide consisting of the particular 10 amino acids of SEQ ID NO: 20, 21, or 22 from among the

1960 amino acids of the nmMHCA polypeptide or from among the 1400 or so amino acids in C-terminal domain of the nmMHCA polypeptide.


For purposes of the analysis here, there is no need to consider any objective criteria of nonobviousness.

Considering all of the *Graham* factors together, it is clear that the present invention – as defined by claim 1 – would not have been obvious to one of ordinary skill in the art at the relevant time in view of the combined disclosures of the Toothaker and Kelley references. Accordingly, the obviousness rejection should be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

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